

**REMARKS**

Claims 2, 3, 5, 7-10, 13, and 15-40 are pending in the present application. Claims 15, 24 and 36 are independent claims.

A Supplemental Information Disclosure Statement is submitted herewith. The references listed are of record in co-pending U.S. Patent Application Serial No. 09/554,793.

Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Per the Examiner's suggestion, claims 2-3, 5, 7-10, and 16-23 are amended to insert "The" as the first word in the claims.

Claim 2 has been further amended to address an antecedent basis issue related to the term "the inner surface".

Claims 2, 8, 10, 15, 21, and 36 have been amended to remove the recitation of "capable".

Claim 7 has been amended to remove the phrase "formed to act as".

Claim 13 has been amended to correct the antecedent basis issue and set forth a step involved in the use of the analytical test element. Specifically, the claim recites that the liquid sample in the detection element is observed to determine whether changes in the detection element exist, wherein the changes relate to a presence of the analyte in the liquid sample. As such, the claim is believed to be a proper process claim under 35 U.S.C. 101.

Claims 15, 19, 21, 24, and 36 have been amended to correct the antecedent basis issues.

Claim 18 has been amended to remove the phrase "all necessary".

Claim 23 has been amended to recite that the intermediate layer is formed to bond the cover and the carrier.

Claim 36 has been amended to recite “observing the liquid sample in the detection element to determine whether changes in the detection element exist following contact with the liquid sample exist, wherein the changes relate to a presence of the analyte in the liquid sample.” Claims 36 as amended is believed to be complete and includes all essential steps.

The amendments to the claims find full support in the specification as originally filed and particularly at Example 2 beginning at page 24, paragraph 3 to page 25, paragraph 1, and Figures 1-6. No new matter is added by virtue of the amendments to the claims. Claims 3, 5, 9, 13, 16, 20, and 22 depend from amended claim 15 and claims 37-40 depend from amended claim 36.

The claims as amended are believed to be sufficiently definite for purposes of 35 U.S.C. 112, second paragraph. As such, reconsideration of the rejection, in light of the amendments, leading to withdrawal of the rejection and allowance of the claims is respectfully requested.

Claims 13, 15, 18-19, 24, and 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Attridge et al. (US Pat. 5,192,502). Attridge et al. discloses a device for use in methods of assay, for example those involving fluorescent moieties.

Claims 15, 24, and 36 have each been amended to recite that the notch extends toward the vent opening. Support for the amendment is found in Figures 1A, 2A, 3A, 4A, 5A, and 6. No new matter is added by virtue of the amendments.

It is submitted that Attridge et al. fails to disclose or suggest a test element that has a capillary channel formed at least partially by the carrier and the detection element, let alone a channel having a notch. At most, Attridge et al. discloses a device with upper and lower plates that define a capillary transport channel. See, the abstract. The lower plate of the device is larger than the upper plate, the lower plate having a section that extends away from the aperture. See, Figures 1-4, 6, 8, and 9.

Attridge et al. is further devoid of description or suggestion of a device having a notch located in a surface forming the channel at an edge of the test element forming the sample application opening, let alone a notch that extends toward the vent opening, as recited by amended claims 15, 24, and 36.

As such, it is submitted that Attridge et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, a detection element, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end . . . wherein a notch is located in a surface forming the channel at an edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed”, as recited by amended claim 15. Claims 13 and 18-19 depend from amended claim 15.

Moreover, Attridge et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, and a detection element cooperating with the carrier to form at least part of a channel formed for capillary liquid transport, the channel having a sample application opening at one end and a vent opening at the other end. . . wherein a surface forming the channel includes a notch at the sample application opening and extending toward the vent opening so that one side of the edge is discontinuous”, as recited by amended claim 24.

Still further, Attridge et al. fails to disclose or suggest a method for determining an analyte in a liquid sample, the method comprising the steps of “providing an analytical test element for the determination of an analyte in a liquid, the test element comprising an inert carrier, a detection element specific for the detection of the analyte, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end . . . wherein a notch is located in a surface forming the channel at the edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed, contacting the test element with the liquid sample at the edge of the sample application opening, which is interrupted by the notch . . . and observing the liquid sample in the detection element to determine whether changes in the detection element exist following contact with the liquid sample exist, wherein the changes relate to a presence of the analyte in the liquid sample”, as recited by amended claim 36.

Claims 37-40 depend from amended claim 36.

Accordingly, the claims as amended are not anticipated and are believed to be patentable over Attridge et al. Reconsideration of the rejections in light of the amendments, leading to withdrawal of the rejections and allowance of the claims is respectfully requested.

Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmer et al. (US Pat. 5,814,522). Zimmer et al. discloses a sample application zone and detection zone arranged on a pile-like complex made of fleece and a porous membrane. See, the abstract. The sample is carried through the membrane or the fleece, whereby the membrane or fleece has capillary structures to allow a liquid transport.

It is submitted that Zimmer et al. fails to disclose or suggest a test element that has a capillary channel formed at least partially by the carrier and the detection element, let alone a channel having a notch. At most, Zimmer et al. discloses a capillary gap (11) positioned between a covering foil (9) and fleece (1) (Figure 3) or between a support foil

(8) and fleece (1) (Figure 4). In each case, “liquid applied to the fleece (1) in the sample application zone (3) distributes rapidly within the fleece (1) and from there it reaches the detection zone (4) of the membrane (2) at right angles to the spreading direction within the fleece area and from there it enters into zone (6) containing the reagent.” See, Column 8 lines 9-14. Nowhere does Zimmer teach a capillary channel formed at least partially by the detection element.

Further, Zimmer et al. is devoid of description or suggestion of a device having a notch located in a surface forming the channel at an edge of the test element forming the sample application opening. Still further, Zimmer et al. lacks a notch that extends toward the vent opening, as recited by amended claims 15, 24, and 36.

As such, it is submitted that Zimmer et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, a detection element, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end . . . wherein a notch is located in a surface forming the channel at an edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed”, as recited by amended claim 15. Claims 2-3, 5, 7-10, 13, and 16-23 depend from amended claim 15.

Moreover, Zimmer et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, and a detection element cooperating with the carrier to form at least part of a channel formed for capillary liquid transport, the channel having a sample application opening at one end and a vent opening at the other end . . . wherein a surface forming the channel includes a notch at the sample application opening and extending toward the vent opening so that one side of the edge is discontinuous”, as recited by amended claim 24. Claims 25-35 depend from amended claim 24.

Still further, Zimmer et al. fails to disclose or suggest a method for determining an analyte in a liquid sample, the method comprising the steps of “providing an analytical test element for the determination of an analyte in a liquid, the test element comprising an inert carrier, a detection element specific for the detection of the analyte, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end . . . wherein a notch is located in a surface forming the channel at the edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed, contacting the test element with the liquid sample at the edge of the sample application opening, which is interrupted by the notch . . . and observing the liquid sample in the detection element to determine whether changes in the detection element exist following contact with the liquid sample exist, wherein the changes relate to a presence of the analyte in the liquid sample”, as recited by amended claim 36.

Claims 37-40 depend from amended claim 36.

Accordingly, the claims as amended are not anticipated and are believed to be patentable over Zimmer et al. Reconsideration of the rejections in light of the amendments, leading to withdrawal of the rejections and allowance of the claims is respectfully requested.

Claims 2, 3, 5, 7, 13, 15, 18-20, 22, 24, and 36-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Vetter et al. (US Pat. 5,851,838). Vetter et al. discloses a test carrier containing a supporting layer (2) with a detection layer (3) arranged thereon containing reagents and an inert layer (4) covering the detection layer (3).

It is submitted that Vetter et al. fails to disclose or suggest a test element that has a capillary channel formed at least partially by the carrier and the detection element, let alone a channel having a notch. At most, Vetter et al. discloses a capillary gap (11) positioned between a covering foil (9) and fleece (1) (Figure 3) or between a support foil (8) and fleece (1) (Figure 4). In each case, “liquid applied to the fleece (1) in the sample application zone (3) distributes rapidly within the fleece (1) and from there it reaches the

detection zone (4) of the membrane (2) at right angles to the spreading direction within the fleece area and from there it enters into zone (6) containing the reagent.” See, Column 8 lines 9-14. Nowhere does Zimmer teach a capillary channel formed at least partially by the detection element.

Specifically, Vetter et al. is devoid of description or suggestion of a test carrier having a notch located in a surface forming the channel at an edge forming the sample application opening. Further, Vetter et al. is also silent as to the existence of a notch that extends toward a vent opening, as recited by amended claims 15, 24, and 36. At most, Vetter et al. discloses that capillary active liquid transport is enabled between the detection layer and inert layer (3, 4), characterized in that the inert layer (4) extends beyond the detection layer. See, the abstract.

As such, it is submitted that Vetter et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, a detection element, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end . . . wherein a notch is located in a surface forming the channel at an edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed”, as recited by amended claim 15. Claims 2-3, 5, 7-10, 13, and 16-23 depend from amended claim 15.

Moreover, Vetter et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, and a detection element cooperating with the carrier to form at least part of a channel formed for capillary liquid transport, the channel having a sample application opening at one end and a vent opening at the other end. . . wherein a surface forming the channel includes a notch at the sample application opening and extending toward the vent opening so that one side of the edge is discontinuous”, as recited by amended claim 24. Claims 25-35 depend from amended claim 24.

Still further, Vetter et al. fails to disclose or suggest a method for determining an analyte in a liquid sample, the method comprising the steps of “providing an analytical test element for the determination of an analyte in a liquid, the test element comprising an inert carrier, a detection element specific for the detection of the analyte, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end . . . wherein a notch is located in a surface forming the channel at the edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed, contacting the test element with the liquid sample at the edge of the sample application opening, which is interrupted by the notch . . . and observing the liquid sample in the detection element to determine whether changes in the detection element exist following contact with the liquid sample exist, wherein the changes relate to a presence of the analyte in the liquid sample”, as recited by amended claim 36. Claims 37-40 depend from amended claim 36.

Accordingly, the claims as amended are not anticipated and are believed to be patentable over Vetter et al. Reconsideration of the rejections in light of the amendments, leading to withdrawal of the rejections and allowance of the claims is respectfully requested.

Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Vetter et al. (US Pat. 6,025,203). Vetter et al. discloses a test carrier containing a supporting layer (2) with a detection layer (3) arranged thereon containing reagents and a network (4) covering the detection layer (3), wherein the network is a plied knitted fabric.

It is submitted that Vetter et al. fails to disclose or suggest a test element that has capillary channel with a notch as recited by amended claims 15, 24 and 36 and in fact teaches away from such a test element. Claims 15 and 36 each recite that the channel extends in the direction of capillary transport *from* the sample application opening *to* at least an edge of the detection element that is nearest to the vent opening. In contrast,



Vetter et al. discloses that attachment of the network to the supporting layer is such that a capillary active liquid transport is possible *from* the detection layer *and into* that part of the network, which is attached to the supporting layer. This capillary active liquid transport must in particular be possible when the detection layer is saturated with liquid. See, Column 4 lines 8-14 and 64-67. Accordingly, Vetter et al. at most teaches a channel that performs in an opposite manner to that of the claimed invention.

Moreover, Vetter et al. is devoid of description or suggestion of a test element having a notch located in a surface forming the channel at an edge of the test element forming the sample application opening, let alone a notch that extends toward the vent opening, as recited by amended claims 15 and 36.

As such, it is submitted that Vetter et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, a detection element, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end, wherein the channel is formed at least partially by the carrier and the detection element and extends in the direction of capillary transport from the sample application opening to at least an edge of the detection element that is nearest to the vent opening and wherein a notch is located in a surface forming the channel at an edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed”, as recited by amended claim 15. Claims 2-3, 5, 7-10, 13, and 16-23 depend from amended claim 15.

Additionally, Vetter et al. fails to disclose or suggest a method for determining an analyte in a liquid sample, the method comprising the steps of “providing an analytical test element for the determination of an analyte in a liquid, the test element comprising an inert carrier, a detection element specific for the detection of the analyte, and a capillary liquid transport channel, the channel including a sample application opening at one end and a vent opening at the other end, wherein the channel is formed at least partially by the

carrier and the detection element and extends in the direction of capillary transport from the sample application opening to at least the edge of the detection element that is nearest to the vent opening and wherein a notch is located in a surface forming the channel at the edge of the test element forming the sample application opening and extends toward the vent opening so that one side of the edge of the test element forming the sample application opening is at least partially discontinuous and a surface opposite to the notch is exposed, contacting the test element with the liquid sample at the edge of the sample application opening, which is interrupted by the notch so that the sample is transported by capillary forces into the channel and wets and penetrates the surface of the detection element that faces the channel, and observing the liquid sample in the detection element to determine whether changes in the detection element exist following contact with the liquid sample exist, wherein the changes relate to a presence of the analyte in the liquid sample”, as recited by amended claim 36. Claims 37-40 depend from amended claim 36.

Regarding claim 24, it is again submitted that Vetter et al. is devoid of description or suggestion of a test element having a notch located in a surface forming the channel at an edge of the test element forming the sample application opening, let alone a notch that extends toward the vent opening, as recited by amended claims 24.

As such, Vetter et al. fails to disclose or suggest an analytical test element comprising “an inert carrier, and a detection element cooperating with the carrier to form at least part of a channel formed for capillary liquid transport, the channel having a sample application opening at one end and a vent opening at the other end, the channel extending from the sample application opening to at least an edge of the detection element that is nearest to the vent opening, and wherein a surface forming the channel includes a notch at the sample application opening and extending toward the vent opening so that one side of the edge is discontinuous”, as recited by amended claim 24. Claims 25-35 depend from amended claim 24.

Accordingly, the claims as amended are not anticipated and are believed to be patentable over Vetter et al. Reconsideration of the rejections in light of the amendments, leading to withdrawal of the rejections and allowance of the claims is respectfully requested.

Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,592,815 to Zimmer. The rejection is respectfully traversed. It is respectfully submitted that the two sets of claims do not read on each other. However, if the rejection is maintained, a terminal disclaimer will be submitted upon receipt of a Notice of Allowance for this matter.

The claims as submitted herein are believed to be in condition for allowance, and allowance of the application is respectfully requested. In addition, it is requested that this paper be considered a request for an extension of time and that all fees due be charged to Deposit Account Number 50-0877 with reference to (RDID 0044 US).

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Respectfully submitted,



Jill L. Woodburn, Reg. No. 39,874  
The Law Office of Jill L. Woodburn, L.L.C.  
128 Shore Drive  
Ogden Dunes, IN 46368-1015  
Telephone: 219-764-4005  
Fax: 219-764-4070